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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/243,030	02/03/1999	MICHAEL GERARD TOVEY	23164-1001-D	1869
1444	7590	06/03/2005	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			COOK, REBECCA	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/243,030	TOVEY, MICHAEL GERARD
	Examiner Rebecca Cook	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 02 March 2005.

2a)  This action is FINAL.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 22-57 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 22-57 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 23, 2005 has been entered.

### ***Claim Rejections - 35 USC § 112 Withdrawn***

In view of the amendment to the claims the earlier rejections under 35 USC 112, first paragraph to claims 36 and 52 is withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-57 are again rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/21229 (Amgen) in view of Iida et al. Amgen discloses a method of treating viral infections (abstract, page 5, lines 26-31, page 13, lines 20-27) using greater than about  $20 \times 10^6$  of interferon. Instant claims 36, 37 and 52 differ over Amgen in reciting "oromucosal contact." However, Amgen discloses (page 13, line 27) that the interferon can be administered nasally, and it is well-known that a product administered

intranasally will contact the oromucosa. Furthermore, it is clear from the specification (page 12, lines 15-19) that nasal administration is contemplated in the instant invention.

Claims 22-24, 30-32, 38-40 and 46-48 differ over Amgen in reciting specific dosage regimens and dosages. However, once a method of use is known it is within the skill of the artisan to determine the optimum dosage regimen. Similarly, once a method of use of a compound is known it is within the skill of the artisan to determine the optimum dosage.

Claims 28 and 44-45 differ over Amgen in reciting type II interferon. However, in the absence of a showing of unexpected results, no unobviousness is seen in the use of type II interferon. Amgen (page 1, lines 13-18) discloses that interferons exhibit antiviral activity and are grouped into three classes, which include IFN-alpha (Type I) and IFN-gamma (Type II).

Applicant argues that nasal administration usually means administration directly into the lungs to make direct contact with virus there and does not mean administering in such a way to remain in the nasopharyngeal cavity. This is not persuasive, since this is not claimed. Furthermore, Iida et al (page 232, left column, second paragraph) discloses that intranasal administration of IL is delivered to the lungs where it activates an immune response.

Applicant's argument regarding oral administration is noted.

It is noted that Applicant has not argued the rejection under 35 USC 103(a) to Amgen in view of Feinberg. However, upon reconsideration said rejection is withdrawn, since the amounts taught by Feinberg are for parenteral administration.

In view of the amendment to claim 37, the earlier rejection under 35 USC 103(a) over 5,286,748 (Eby) is withdrawn.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook



Primary Examiner  
Art Unit 1614

May 31, 2005